

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No.	:	10/563,785	Confirmation No.:	2982
Appellant	:	NOLTING, John		
Filed	:	April 25, 2006		
TC/A.U.	:	1615		
Examiner	:	HELM, Caralynne E.		
Docket No.	:	P1394		
Customer No.	:	28390		
Title	:	COATED STENT WITH TIMED RELEASE OF MULTIPLE THERAPEUTIC AGENTS TO INHIBIT RESTENOSIS ADJACENT TO THE STENT ENDS		

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313

REPLY BRIEF

Dear Sir:

Please consider Appellant's reply brief as follows:

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1. STATUS OF CLAIMS

Claims 1-3, 7-12, 14, 15, and 18-32 are pending.

Claims 30-32 were rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement.

Claims 12, 14, 15, and 18-20 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent Publication No. 2003/0153983 to Miller, *et al.* (the *Miller* publication) in view of U.S. Patent No. 6,471,980 to Sirhan, *et al.* (the *Sirhan C* patent).

Claims 1-3, 7-12, and 19-29 were rejected under 35 U.S.C. §103(a) as being unpatentable over the *Miller* publication in view of the *Sirhan C* patent and further in view of U.S. Patent Publication No. 2003/0033007 to Sirhan, *et al.* (the *Sirhan B* publication) in view of U.S. Patent Publication No. 2004/0002755 to Fischell, *et al.* (the *Fischell* publication).

Claims 12 and 31 were rejected under 35 U.S.C. §103(a) as being unpatentable over the *Miller* publication in view of the *Sirhan C* patent and further in view of U.S. Patent Publication No. 2004/0249449 to Shanley, *et al.* (the *Shanley* publication).

Claims 1, 23, 30, and 32 were rejected under 35 U.S.C. §103(a) as being unpatentable over the *Miller* publication in view of the *Sirhan C* patent and further in view of the *Sirhan B* publication in view of the *Fischell* publication and further in view of the *Shanley* publication.

Claims 1-3, 7-12, 14, 15, and 18-32 are the claims on appeal.

2. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Whether claims 30-32 failing to comply with the written description requirement under 35 U.S.C. §112, first paragraph.

Whether claims 12, 14, 15, and 18-20 are unpatentable under 35 U.S.C. §103(a) over U.S. Patent Publication No. 2003/0153983 to Miller, *et al.* (the *Miller* publication) in view of U.S. Patent No. 6,471,980 to Sirhan, *et al.* (the *Sirhan C* patent).

Whether claims 1-3, 7-12, and 19-29 are unpatentable under 35 U.S.C. §103(a) over the *Miller* publication in view of the *Sirhan C* patent and further in view of U.S. Patent Publication No. 2003/0033007 to Sirhan, *et al.* (the *Sirhan B* publication) in view of U.S. Patent Publication No. 2004/0002755 to Fischell, *et al.* (the *Fischell* publication).

Whether claims 12 and 31 are unpatentable under 35 U.S.C. §103(a) over the *Miller* publication in view of the *Sirhan C* patent and further in view of U.S. Patent Publication No. 2004/0249449 to Shanley, *et al.* (the *Shanley* publication).

Whether claims 1, 23, 30, and 32 are unpatentable under 35 U.S.C. §103(a) over the *Miller* publication in view of the *Sirhan C* patent and further in view of the *Sirhan B* publication in view of the *Fischell* publication and further in view of the *Shanley* publication.

3. ARGUMENTS

The Appellant respectfully submits that claims 1-3, 7-12, 14, 15, and 18-32 are allowable over the cited references under 35 U.S.C. §103(a), and that the rejection of claims 1-3, 7-12, 14, 15, and 18-32 should be reversed. The Appellant further respectfully submits that claims 30-32 comply with the written description requirement under 35 U.S.C. §112, first paragraph.

The Appellant re-asserts the argument of the Appellant's Brief dated September 27, 2010 (hereinafter Appellant's Brief) and presents the following arguments in response to the Examiner's Answer dated December 13, 2010 (hereinafter Examiner's Answer).

35 U.S.C. §112 Rejections

Claims 30-32 have been rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement, particularly, for not having a written basis for the new limitation that the plurality of therapeutic agents is released from the plurality of therapeutic coatings after the adjacent overlying timing coating has completely eroded. The Appellant respectfully disagrees and asserts that the written description in the specification fully supports the limitation.

Pages 14 and 15 of the Response to Argument section of the Examiner's Answer maintains that "[w]hile the arrow symbols in this figure clearly translate to the passage of time corresponding to the timing coatings, it is not clear that they represent the complete or partial erosion of these layers," and that "[a]lthough paragraphs 38 and 40 discuss the erosion of the timing coatings occurring before the release of the therapeutic agent for the adjacent underlying coating, there is no statement or suggestion that the timing coating must be completely gone before the release of the therapeutic commences." The Appellant respectfully asserts that the description must be considered as a whole and that the description as a whole supports each of the plurality of therapeutic agents being released from the plurality of therapeutic coatings after the adjacent overlying timing coating has completely eroded, as claimed.

Figure 3 of the Appellant's application shows the action of each timing coating alternating with the action of each therapeutic coating. Figure 4 of the Appellant's application shows release of each therapeutic coating alternating with erosion of each timing coating. Paragraphs [0038] and [0040] of the Appellant's application disclose that the therapeutic agent is released after the timing coating has eroded. See Figures 3, 4; paragraphs [0026]-[0033], [0037]-[0041].

The combination of the graphic representation of Figure 3, the flowchart of Figure 4, and the statements in paragraphs [0038] and [0040] clearly support the limitation in claims 30-32, so that claims 30-32 comply with the written description requirement. In accordance with the objective standard for determining compliance with the written description requirement, the description clearly allows persons of ordinary skill in the art to recognize that he or she invented what is claimed. *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989).

Reversal of the rejection of claims 30-32 under 35 U.S.C. §112 as failing to comply with the written description requirement is respectfully requested.

35 U.S.C. §103 Rejections

Regarding U.S. Patent Publication No. 2003/0153983 to Miller, *et al.* (the *Miller* publication) in view of U.S. Patent No. 6,471,980 to Sirhan, *et al.* (the *Sirhan C* patent), as used together or in combination with additional references in the rejection of claims 1-3, 7-12, 14, 15, and 18-32 under 35 U.S.C. §103(a):

Pages 15-17 of the Response to Argument section of the Examiner's Answer asserts that "Appellant summarizes some of the teachings found in Miller *et al.* and Sirhan *et al.* C; however these embodiments are a subset of those taught and suggested by these references," that "Miller *et al.* also teach that these annular layers are biodegradable (and therefore erodible), indicating the presence of additional release mechanisms in the layered system," and

that " Sirhan et al. C also teaches degradable/bioerodible rate controlling layers over the drug reservoir, indicating an additional release mechanism." The Appellant respectfully disagrees.

Although the *Miller* publication and the *Sirhan C* patent disclose biodegradable layers, the only layers disclosed as barrier or rate limiting layers allow diffusion of the therapeutic agent through the barrier or rate limiting layer. The *Miller* publication discloses that the first and second barrier layers that enclose the first annular layer are typically less permeable than the biocompatible matrix polymer and, thereby, control the rate of diffusion of the bioactive and optional therapeutic agents from the device to the external environment. *See* paragraph [0056]. The *Sirhan C* patent discloses mycophenolic acid may be released by diffusion through the rate limiting barrier. *See* column 5, lines 25-32. Diffusion allows simultaneous release of drugs from the multiple layers as therapeutic agents from underlying layers diffuse across outer layers, so the therapeutic agents cannot be released exclusively and sequentially as claimed.

Reversal of the rejection of claims 1-3, 7-12, 14, 15, and 18-32 under 35 U.S.C. §103(a) is respectfully requested.

4. SUMMARY

The Appellant respectfully submits that claims 1-3, 7-12, 14, 15, and 18-32 fully satisfy the requirements of 35 U.S.C. §112, first paragraph, and 35 U.S.C. §103. In view of the foregoing, reversal of the rejection of claims 1-3, 7-12, 14, 15, and 18-32 is respectfully requested.

Respectfully submitted,

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